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(19) (CA) **APPLICATION FOR CANADIAN PATENT** (12)

(54) Stent

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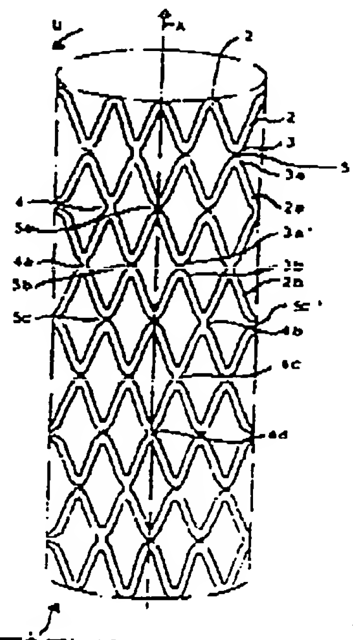
(54) Bezeichnung: STENT

(57) Abstract

The invention proposes a stent that has easier and better pliability and greater flexibility than known stents, owing to the fact that the stent has multiple meandrous webs (2, 2a, 2b, 2c) arranged successively in the axial direction (A) and spanning its circumference (U), and to the fact that at least two regions (3, 3a, 3'a, 3b) of each meandrous web (2, 2a, 2b, 2c) that face each other and are not mutually connected are situated in the circumferential direction (U), between regions (3, 3a, 3'a, 3b) of the meandrous webs (2, 2a, 2b, 2c) that face each other in the axial direction and are joined by connecting segments (4, 4a, 4b, 4c).

(57) Zusammenfassung

Die Erfindung schlägt einen Stent vor, der eine leichtere und bessere Biegsamkeit und höhere Flexibilität aufweist als bekannte Stents, was dadurch erreicht wird, daß er mehrere in Achsrichtung (A) hintereinander angeordnete, sich über seinen Umfang (U) erstreckende Mäanderbahnen (2, 2a, 2b, 2c) aufweist, daß zwischen einander in Achsrichtung zugewandten und durch Verbindungsabschnitte (4, 4a, 4b, 4c) miteinander verbundenen Bereichen (3, 3a, 3'a, 3b) der Mäanderbahnen (2, 2a, 2b, 2c) in Umfangsrichtung (U) mindestens jeweils zwei einander zugewandte, nicht miteinander verbundene Bereiche (3, 3a, 3'a, 3b) jeder Mäanderbahn (2, 2a, 2b, 2c) angeordnet sind.



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Stent

The invention relates to a stent.

Such stents or implantable catheters, which can be inserted in a body cavity, a vessel or the like, can be made from plastic or an inert metal, such as steel or nickel-titanium alloys. Such stents are in particular known as endovascular or endoluminal stents or intraluminal tubes. The stents are used for instance in widening the ureter in the prostate region in the case of benign prostate hyperplasia (BPH) or in the case of sclerotic blood vessels for widening and keeping open the same. The stents have material areas and gaps between them. Thus, the parietal tissue of the organ kept open can grown round the stent. Stents can have a spiral construction or can be in the form of a helically wound coil. They can also be made from woven, knitted or braided wire or plastic material. Such stents can have memory characteristics, such as occur, for instance, with certain nickel-titanium alloys (nitinol).

A problem with such stents is their limited bendability, particularly on introducing through narrow organs, such as blood vessels, at the point where a widening can take place. There is a risk that on bending the stent it bends in the centre as a result of the action of axially vertically directed forces, in that its cross-sectional area is reduced in the direction of the acting forces, but is widened perpendicular thereto and to the axial direction thereof. This can make insertion more difficult and can also damage the surrounding tissue, particularly if the stent is to be inserted in a bend area of the vessel or the like. Stents are relatively stiff and inflexible. This more particularly applies with stents having a rhombic structure, which are e.g. produced by cutting from nickel-titanium sheeting and have memory characteristics.

The problem of the invention is consequently to provide a stent, which has a high bending flexibility in the case of axially vertically acting forces and which is in particular subject to no deformations of its contour, particularly suffering no cross-sectional changes in the case of bending.

According to the invention this problem is solved by a stent, which is characterized in that it has several axially succeeding meander paths extending over its circumference, that between axially facing areas of the meander paths interconnected by connecting portions in the circumferential direction there are at least two facing, non-interconnected areas of each meander path.

Due to the fact that with such a stent and with several axially succeeding material paths guided in meander-like manner over the circumference facing or directed towards one another, adjacent areas of two adjacent meander paths are not interconnected in all cases, but instead between such interconnected areas there are circumferentially at least two non-interconnected areas, a higher flexibility is obtained than would be the case with a stent in which all the facing, adjacent areas of two adjacent meander paths were firmly interconnected. This not only leads to a higher flexibility, but it is in particular achieved that no cross-section deformation occurs at bends under the action of axially vertical forces.

An important advantage of the invention is that a high bendability is achieved without multilayer material crossing points, such as is the case in knitted, woven and braided structures. Due to the fact that there are no such material crossing points, the stent according to the invention grows between into the tissue. It also significantly reduces or eliminates the risk of the occurrence of thromboses, particularly in the vascular region.

According to a preferred development the connecting portions of axially succeeding meander paths are reciprocately displaced in the circumferential direction and in particular the connecting portions are circumferentially displaced by half a meander period, so that the desired axial strength is retained or obtained.

The meander paths can be formed in numerous different ways. Thus, according to preferred developments, the meander paths are zig-zag-like (with peaks), the meander paths are sinusoidal and that the meander paths have an oval construction. According to further preferred developments facing areas of

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the meander paths are aligned in the axial direction and/or that the width of the connecting areas in the circumferential direction is no larger than the width of the legs of the meander paths.

The stent is preferably self-expanding and is made from a memory metal material. In the low temperature state (well below body temperature), the individual meander legs engage with one another, whereas in the high temperature state (below but closer to body temperature) the stent is radially widened.

Further advantages and features of the invention can be gathered from the claims and the following description of the inventive stent with reference to the attached drawings, wherein show:

Fig. 1 a preferred development of the stent according to the invention in its low temperature or insertion configuration;

Fig. 2 the stent of Fig. 1 in its high temperature or positioning configuration;

Fig. 3 a diagrammatic representation of a stent separated longitudinally at its welding positions and laid out flat in order to better illustrate the connection of the successive, axial, zig-zag meander webs;

Fig. 4 a slotted plate for producing a stent according to the invention.

In the represented embodiment the stent 1 according to the invention has a cylindrical shape, the outer contour of the stent being indicated by broken lines S in Fig. 2.

In place of a cylindrical design the stent 1 can also have a conical, biconical, frustum-shaped or other contour. It always has an axis of symmetry A, which determines the axial direction. The circumferential direction is indicated by the arrow U.

As can in particular be gathered from Figs. 2 and 3, the stent 1 according to the invention comprises a number of meander paths 2, 2a, 2b succeeding one another in the axial direction A. In the circumferential direction the meander paths 2, 2a, 2b are arranged in such a way that in each case facing, adjacent peak areas 3, 3a or 3'a, 3b of in each case juxtaposed meander paths 2, 2a, 2b are axially aligned.

Figs. 2 and 2a clearly show that not all the facing, adjacent peak areas 3, 3a, 3'a, 3b of the meander paths 2, 2a, 2b are interconnected by connecting areas 4, 4a, 4b, 4c, 4d, but between such connecting areas 4 to 4d of two adjacent meander paths 2, 2a are circumferentially provided several gaps 5, 5', 5a, 5b, 5b'. This leads to a high flexibility of the stent according to the invention. It is in particular achieved that when the stent 1 is bent at right angles to its longitudinal axis A the central area does not bend in such a way that it loses its cross-sectionally, substantially circular contour and is pressed flat in the centre in the action direction of the forces and perpendicular to the action direction of the forces is not widened in the centre of its longitudinal extension as is the case with conventional stents, where all the facing adjacent peak areas 3, 3a etc. of juxtaposed meander turns are firmly linked by connecting areas 4, 4a etc.

The connecting areas 4, 4a etc. are in one piece with the remaining part of the stent, particularly the meander paths 2, 2a etc. and their adjacent areas 3, 3a.

It can be gathered from Fig. 1 that the substantially rhombic free spaces formed between the legs of the meander path 2, 2a etc. in the high temperature setting taper to slots in the low temperature setting and the legs of the meander paths 2, etc. are substantially parallel to one another.

Fig. 3 also shows that the circumferential thickness of the connecting areas 4, 4a, 4b, 4c is no greater than the thickness of the individual legs of the meander paths 2, 2a, etc. The areas 7, 7' or 7a, 7a' are welded areas, which

in the closed position of the stent shown in Fig. 3 are interconnected by welded joints.

Fig. 4 shows a slotted plate from which the stent according to the invention can be produced. The stent is made from a nickel-titanium alloy, such as nitinol. In a flat plate the openings or slots 11, as shown in Fig. 4, are produced in that circumferentially adjacent slots are in each case displaced by approximately half their length in the axial direction A. In the central area of each slot 11 the latter is provided with a widening 12, so that the material bounding the widening 12 in the circumferential direction is reduced roughly to the width of the material left between the slots. If the portions 13 are left, they later form the connecting portions 4, 4a, etc., or in the areas where the portions 13 are removed, the free spaces or gaps 5, 5a, etc are created.

After producing the plate in the form shown in Fig. 4 initially all the portions 13 are left. Only to the left is it indicated in Fig. 4 how subsequently, i.e. after producing the stent, as shown in Figs. 1 and 2, the separations are formed for creating the gaps 5.

The plate shown in Fig. 4 is bent to form a cylinder, so that the two edges 14, 15 are in contact. At the welding points 7, 7' the welding joints are made and as a result initially a stent is formed in its low temperature position corresponding to Fig. 1. This is followed by a heat treatment, so as to give memory characteristics to the resulting stent, so that after raising the temperature to a predetermined ambient temperature, which is below the temperature of the human body, it can widen to its high temperature position corresponding to Fig. 2.

After producing and heat treating the stent in this way, the bridges 13 are removed in the desired manner, so that the connecting areas or webs 4, 4a, etc. or free spaces 5, 5', 5a, etc. are formed, in the manner described hereinbefore. In Fig. 3 between two circumferentially succeeding connecting areas or webs 4, 4a are in each case formed two free spaces 5 of adjacent, facing areas 3, 3a of the meander turns 2, 2a. The portions between the

joining areas 4 in the circumferential direction can also be made larger. As a rule, there should be at leat two free spaces 5 between two circumferentially succeeding webs 4.

The invention provides a highly flexible stent, which can follow all the bends without any deterioration.

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CLAIMS

1. A stent from a sheet metal made from a memory metal alloy having a low temperature configuration and a radially expanded high temperature configuration, with a plurality of meandrous webs (2, 2a, 2b, 2c) arranged successively in axial direction (A) and extend over its circumference (U), wherein at least two regions (3, 3a, 3'a, 3b) or each meandrous web (2, 2a, 2b, 2c) that face each other and are not mutually connected are situated in the circumferential direction (U) between regions (3, 3a, 3'a, 3b) of the meandrous webs (2, 2a, 2b, 2c) that face each other in the axial direction and are joined by connecting segments (4, 4a, 4b, 4c), characterized in that — in said low temperature configuration — the flanks of the meandrous webs abut against each other.

2. Stent according to claim 1, characterized in that the connecting portions (4,4a,4b,4c) of axially succeeding meander paths (2,2a,2b,2c) are reciprocately displaced in the circumferential direction (U).

3. Stent according to claim 2, characterized in that the connecting portions (4,4a,4b,4c) are displaced by half a meander period in the circumferential direction (U).

4. Stent according to any one of the claims 1 to 3, characterized in that the meander paths (2,2a,2b,2c) have a zig-zag construction with peaks.

5. Stent according to any one of the claims 1 to 3, characterized in that the meander paths are sinusoidal.

6. Stent according to any one of the preceding claims, characterized in that the meander paths are oval.

7. Stent according to any one of the preceding claims, characterized in tat the facing areas (3,3a,3'a,3b) of the meander paths (2,2a,2b,2c) are aligned in the axial direction (A).

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8. Stent according to any one of the preceding claims, characterized in that the width of the connecting areas (4,4a,4b,4c) in the circumferential direction (U) is no greater than the width of the legs of the meander paths (2,2a,2b,2c).

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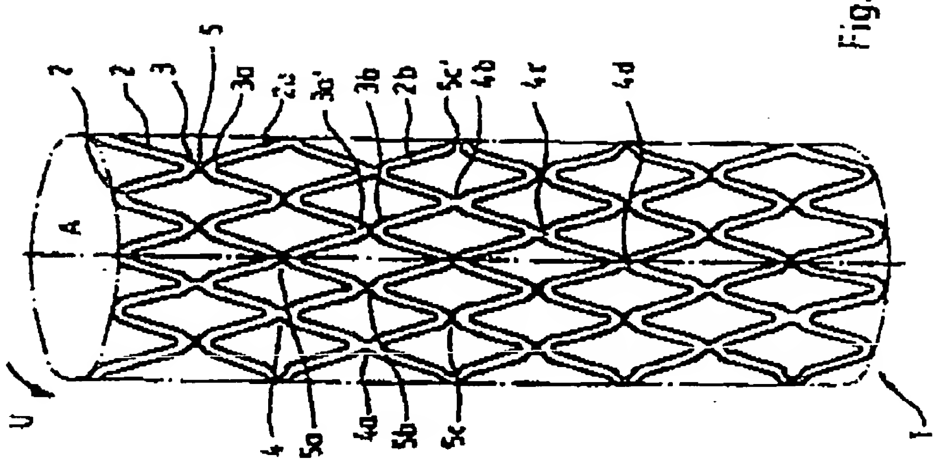

Fig. 2

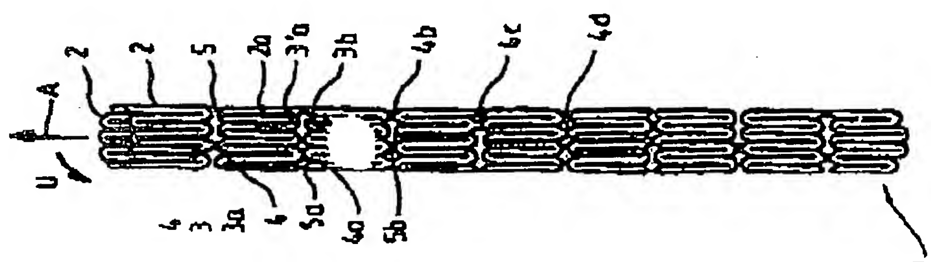

Fig. 1

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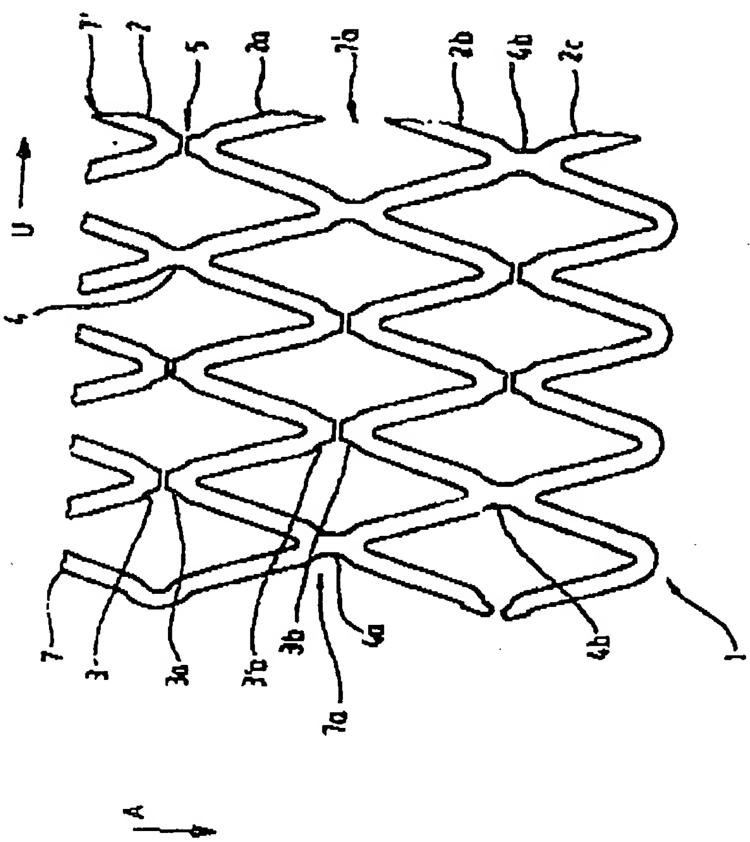

Fig. 3

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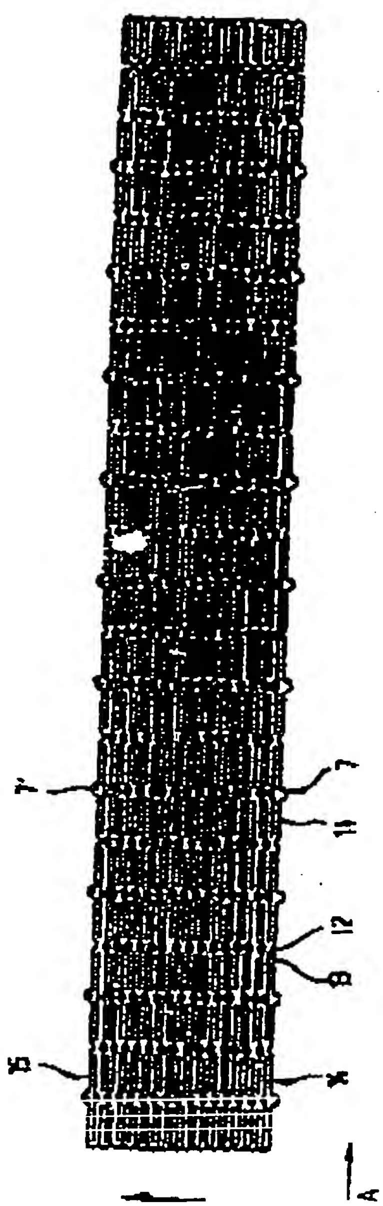

Fig.4

Gaaling, Sinatky & Henderson